REMARKS

I. Status of Claims

Claims 9 and 12-19 are pending in this application on the merits and stand rejected. Claim 11 is withdrawn from consideration. Claim 9 is amended herein without prejudice or disclaimer. Support for the amendments to claim 9 can be found throughout the original specification, for example at paragraph [0031]. Claim 19, directed to the elected species N-(diaminomethylene)-9-hydroxy-9H-fluorene-2-carboxamide, is new. Support for claim 19 can be found, for example, on page 32 of the as-filed specification. No issue of new matter is raised by these amendments.

II. Interview

Applicants wish to thank Examiner Orwig for the courtesies extended to Applicants representatives in the telephonic interview dated August 27, 2010. During the interview, the outstanding rejections and possible claim amendments were discussed.

III. Information Disclosure Statement

The Office lined through the documents JP 5-194359 and JP 9-510216 in the Information Disclosure Statement filed on March 19, 2010, stating that the references were "not considered because they were not provided or were not provided in English." (Non-final Office Action dated September 9, 2009, ("Office Action") page 2.) Although Applicant respectfully disagrees with the Office's interpretation of what constitutes a responsive concise statement of relevance pursuant to M.P.E.P. § 609.04(a), Applicant submits herewith English language abstracts of theses references (JP 5-194359 and JP 9-510216). Accordingly, Applicant respectfully requests the Office to indicate that it has

considered the foreign documents and their respective English Abstracts on the Information Disclosure Statement submitted herewith.

Moreover, Applicant notes that Information Disclosure Statement submitted on September 6, 2006, does not appear to have been considered by the Examiner. Consequently, Applicant respectfully requests that the Examiner consider the documents submitted on that day and return a properly marked copy of the SB/08 form to the Applicant.

IV. Election of Species

The Office has acknowledged the election of Group IV (claim 9). Applicants acknowledge the Office's statement that the "elected species for the single compound N-(diaminomethylene)-9-hydroxy-9H-fluorene-2-carboxamide indicated that this compound was free of the prior art." Office Action at 2.

V. Objection to Specification

The Office has objected to the specification because the claim for domestic priority to PCT/JP2005/002946 has not properly been made. Applicants submit that this objection is rendered moot by the Amendment to the Specification herein.

VI. Rejections under 35 U.S.C. § 112

A. Written Description

The Office rejects claims 9 and 11-18 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement. The office contends "the claims encompass *any* dual antagonist for the 5-HT_{2B} and 5-HT_7 receptor (i.e. both single compounds having dual activity and separate compounds administered together), but applicants were clearly not in possession of any and all such compounds at the time of filing." Office Action at 5. Applicants respectfully disagree for the reasons that follow.

"An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." MPEP 2163 II.A.3(a) (citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000)) (emphasis added). "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." M.P.E.P. § 2163 (I), citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1563, 1572 (Fed. Cir. 1997). Applicants further note that "[t]here is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96" *Id.*

Applying the standards for written description, Applicants submit that the rejection under § 112 is improper in this case. Even though there is no *in haec verba* requirement for written description, Applicants have described the claimed invention with all of its limitations *ipsis verbis*. For example, the written description requirement for claim 9 is satisfied by the disclosures at paragraphs [0022], [0031], and [0032]. Moreover, the Examiner has not met his burden "after a thorough reading and evaluation of the content of the application, [of presenting] evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP 2163 II.A. Accordingly, because there is full literal support for the claims, unquestionably, the written description requirement is satisfied here.

In response to the Examiner's contention, inter alia, that "if a biomolecule is described only by a functional characteristic, without any correlation between function and structure of the sequence, it is 'not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence," Applicants submit that the Examiner's statement is irrelevant to the pending claims as no DNA sequence is claimed in the present application. *See* Office Action at 7.

Even without literal support, as is present here, the law clearly states that the written description requirement can be satisfied in several ways, including:

"[i] sufficient description of a representative number of species by actual reduction to practice,

[ii] reduction to drawings,

[iii] or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties,

[iv] by functional characteristics coupled with a known or disclosed correlation between function and structure,

[v] or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus."

M.P.E.P. § 2143 I.A.3(a)(ii) (citing Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406) (internal citations omitted). Such showings are relevant when an Applicant has failed to described the claimed genus, not as in the present case, where *ipsis verbis* support exists for the genus as claimed.

In the present case the genus is fully described since the specification includes a "description of sufficient, relevant, identifying characteristics" so that "a person skilled in

the art would recognize that the inventor had possession of the claimed invention." MPEP 2163 II.A.3(a). To the extent that the Examiner contends that "Applicants have failed to provide sufficient description of the various compounds" that may be within the scope of claim 9, 35 U.S.C. § 112 makes no such requirement, either based upon written description or enablement. Indeed, there is no requirement that Applicants literally describe any species within a claimed genus if Applicants provide a sufficient written description of the genus to enable one to make and use the invention.

Questions of "how to make and how to use the invention" arise not under the written description requirement, but under the enablement requirement. *See* MPEP § 2164, *Ariad v. Lilly*, 94 USPQ.2d 1161, 1167 (Fed. Cir. 2010). To the extent the Examiner implies the claims are not enabled by the specification, Applicants submit that the specification demonstrates that a person of skill in the art could make and use the invention as claimed without undue experimentation. For example, as is known to persons of skill in the art, "selective dual antagonistic compounds can easily be found by screening a large amount of compounds to determine receptor affinity according to a method as shown in Reference Examples." *See, e.g.,* Applicants specification at [0041]. Such methods are "routine and efficient." *See id.* "What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." MPEP 2163 II.A.3(a)(citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.).

Applicants submit that the claims are fully supported by the specification and that there is no issue of written description in this case. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112.

B. Enablement

The Office also rejects claims 9 and 12-18 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirement. The Office contends that the specification "does not reasonably provide enablement for prophylaxis or prevention of [migraines]," but admits that the specification is "enabling for treatment or inhibition of migraines." Office Action at 8. Therefore, to expedite prosecution, Applicants have amended claim 9 to recite a "method for treatment or inhibition of migraines . . . ." Applicants understand that treatment or inhibition of migraines according to the claimed method includes administering a composition to a symptomatic or an asymptomatic patient to reduce the frequency of attack or severity of pain. *See* Specification at [0031] and [0074]. Applicants also understand that "treatment or inhibition of migraines," as set forth in the amended claims refers to the partial or complete treatment or inhibition of migraine in a migraine patient or a patient who has been diagnosed to be migraine or in whom periodical attacks of migraine occur. Specifically, inhibition includes the complete inhibition of attack and cessation of pain. Accordingly, in view of the amendment, Applicants respectfully request withdrawal of this rejection.

VII. Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 9 and 12-18 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,440,988 ("Craig"). Office Action at 12-13. The Office contends Craig discloses "a method of treating a subject comprising administering a therapeutically effective amount of an antagonist that binds to both 5-HT_7 and 5-HT_{2B} receptors. *Id* at 12. The Office concludes "Craig teaches the only active step of the

instantly claimed method (i.e. claim 9), and teaches a pharmacokinetic profile that matches that claimed except for being silent as to the affinity of the compounds at the M1 (muscarinic) receptor." *Id.* Applicants respectfully disagree and traverse for the reasons that follow.

A claim is not anticipated unless "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. *Verdegaal Bros. v. Union Oil Co. of Cali-fornia*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Regardless of the teachings of pharmacokinetics and any inherent properties of the antagonists of Craig, the reference fails to anticipate the claims because it does not teach each and every element of the pending claims. Specifically, claim 9, as amended, recites "treating or inhibiting migraine in a migraine patient or a patient who has been diagnosed to be migraine or in whom periodical attacks of migraine occur." Craig, in contrast to the pending claims, treats disorders of the bladder, not migraine patients. *See, e.g.,* Craig at Title, Abstract, and col. 4, lines 38-56. Craig is silent with respect to patients in need of treatment or inhibition of migraine. Therefore, Craig fails to teach this element, and accordingly cannot anticipate the pending claims. Applicants respectfully request withdrawal of this rejection.

VII. Double Patenting Rejection

The Examiner provisionally rejects claims 9 and 12-18 on the ground of non-statutory obviousness type double patenting as being unpatentable over claim 22 of copending Application No. 11/997,956 (the '956 application).

Although the Applicants do not necessarily agree with the Office's contentions, Applicants note that the '956 application is currently subject to restriction, and claim 22, the sole claim of the '956 application cited by the Examiner (drawn to a method for preventing migraine), is a non-elected claim. See '956 application, Response to Election/Restriction, filed Aug. 5, 2010. Applicants contend that since this rejection is merely provisional and is not ripe in view of the non-election of the relevant claim in the '956 application, no terminal disclaimer is necessary before the claims of the instant application can be allowed. Further, should claim 22 of the '956 patent ever be elected, that would be a more appropriate time to consider whether any double patenting issues exist.

VIII. Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration and the timely allowance of the claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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Dated: September 28, 2010

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